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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/684,742	GHETTI ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24-28* is/are pending in the application.

4a) Of the above claim(s) *1-16,22,24 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21,25,26 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10-14-03 & 9-1-04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-17-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of group IX, claims 17-21, in the reply filed on 5-22-06 is acknowledged. The traversal is on the ground(s) that claim 17 has been amended to recite transgenic mouse comprising an altered FTL gene and the screening method of claims 22 and 27 requires the use of the transgenic mouse of claims 17 or 18 respectively, therefore, there is no serious burden for examiner to search both groups IX and X. This is not found persuasive because the transgenic mouse of group IX can be used to produce a recombinant protein instead of being used as an animal model for screening agents. Groups IX and X have different classifications and require separate search. The search for groups IX and X would not be coextensive. There is serious burden for examiner to search both groups IX and X.

The requirement is still deemed proper and is therefore made FINAL.

Applicants' amendment filed 5-22-06 has been entered. Claims 17, 18 and 22 have been amended. Claim 23 has been canceled. Claims 25-28 have been added. Claims 1-22 and 24-28 are pending. Claims 17-21, 25, 26 and 28 are under consideration.

It is noted that groups IX and X are patentably distinct from each other and only group IX is considered. Therefore, the newly added claim 27, which concerns the subject matter of group X, will not be considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 18, 19, 26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "PGK" and "CMV" in claim 18 are vague and renders the claims indefinite. The terms "PGK" and "CMV" are an abbreviation and can stand for various meanings. Spelling out the terms "PGK" and "CMV" would be remedial. Claims 19, 26 and 28 depend from claim 18.

4. Claim 25 recites the limitation "a host cell isolated from the transgenic mouse of claim 17" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 17 fails to recite any transgenic mouse.

5. Claim 28 recites the limitation " a host cell isolated from the transgenic mouse of claim 18" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 18 fails to recite any transgenic mouse.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 17-21, 25, 26 and 28 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The claims are directed to a transgenic animal comprising an altered ferritin light chain (FTL) gene or altered ferrintin light chain gene comprising SEQ ID No. 1 and is operably linked to a promoter as recited in claim 18, progeny of said transgenic animal, and a host cell isolated from said transgenic animal.

The specification discloses the nucleotide sequence of SEQ ID No. 1 encoding a human ferritin light subunit variant protein. The specification defines the term "animal" to include all vertebrate animals except humans (e.g. p. 38, lines 26-27). The specification provides general assertions that the claimed transgenic mice may be used to develop screening methods to screen therapeutic agents to identify those capable of modulating FTL variant activity (e.g. bridging p. 42-43).

The asserted utility for the claimed transgenic animal does not appears to be specific and substantial because the evidence of record has not provided any suggestion of a correlation between any phenotype of the claimed transgenic animals or mice, the altered ferritin light chain gene, and a disease or a disorder. The specification fails to provide a correlation between the altered ferritin light chain gene and phenotype, if any, of the claimed transgenic animals or mice or a correlation between the phenotype, if any, of the claimed transgenic animals or mice and any ferritin light chain gene related disease or disorder. The asserted utility for the claimed transgenic mouse for developing screening methods to screen therapeutic agents to identify those capable of modulating FTL variant activity does not appear to be specific and substantial because

the evidence of record has not provided any suggestion whether there is any FTL variant activity in the claimed transgenic animals or transgenic mice. It is unclear whether the claimed transgenic animals or mice have any phenotype or not and whether the altered FTL is expressed or to what level it is expressed in said transgenic animals or transgenic mice. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the transgenic animals or mice embraced by the claims. Therefore, the utility of for developing screening methods to screen therapeutic agents to identify those capable of modulating FTL variant activity is not apparent.

The specification fails to disclose any phenotype of the claimed transgenic animal or transgenic mouse. A transgenic animal or transgenic mouse having no phenotype is indistinguishable from a wild-type animal or mouse and does not have a specific and substantial utility or a well-established utility because one skilled in the art would not know where and what to look for in using said transgenic animal or mouse. A substantial utility is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. Absent the phenotype of the claimed transgenic animal or mouse and the correlation between a phenotype of the claimed transgenic animal or mouse and a particular disease or disorder, no "real world" use of the claimed transgenic animal or mouse has been established. Therefore, the claimed transgenic animal or mouse lacks a specific and substantial or a well-established utility.

The host cell of claims 25 and 28 are isolated from the claimed transgenic mice. The claimed cell lacks a specific and substantial utility for the reasons set forth above.

In light of the above, the skilled artisan would not find the asserted utility of the transgenic animals or mice, and host cell encompassed by the claims to be specific and substantial or well established.

Claims 17-21, 25, 26 and 28 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 17-21, 25, 26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a transgenic animal comprising an altered ferritin light chain (FTL) gene or altered ferrintin light chain gene comprising SEQ ID No. 1 and is operably linked to various promoter as recited in claim 18, progeny of said transgenic animal, and a host cell isolated from said transgenic animal.

The specification discloses the nucleotide sequence of SEQ ID No. 1 encoding a human ferritin light subunit variant protein. The specification defines the term "animal" to include all

vertebrate animals except humans (e.g. p. 38, lines 26-27). The specification fails to provide adequate guidance and evidence for how to make the claimed transgenic animals or mice comprising an altered FTL gene. The specification also fails to disclose any phenotype of the claimed transgenic animals or transgenic mice. A transgenic animal or transgenic mouse having no phenotype is indistinguishable from a wild-type animal or mouse and one skilled in the art at the time of the invention would not know how to use the claimed transgenic animals or mice.

The level of one of ordinary skill in the art is high regarding making transgenic animal. The art of transgenics at the time of the invention held that the resulting phenotype of a transgenic animal or mouse was unpredictable at the time of the invention. Kappel et al., 1992 (Current Opinion in Biotechnology, Vol. 3, p. 548-553) reports that the individual gene of interest, promoter, enhancer, coding or non-coding sequences present in the transgene construct, the site of integration, etc., are the important factors that governs the expression of a transgene (e.g. p. 549)). Wall, R. J., 1996 (Theriogenology, Vol. 45, p. 45-68) states that "[o]ur lack of understanding of essential genetic control elements makes it difficult to design transgenes with predictable behavior" (e.g. p. 61, last paragraph), and "transgene expression and the physiological consequences of transgene products in livestock are not always accurately predicted in transgenic mouse studies" (e.g. p. 62, first paragraph). Strojek et al., 1988 (Genetic Engineering: Principles and Methods, Vol. 10, pp. 221-246) points out that "genetic and species-specific conditions can cause different limitations or gene integration efficiency" and "transgenic mouse work alone is only of limited value when problems arising in the production of transgenic livestock are to solved, particularly when there is a necessity of finding cis-acting factors which are suitable for appropriate gene expression in a given species" (e.g. p. 238-239).

Further, the genetic background of the transgenic mice has a large impact on the resulting phenotype of the transgenic animals or mice. Sigmund, C., June 2000 (Arterioscler. Thromb. Vasc. Biol., p. 1425-1429), reports that variation in the genetic background contributes to unpredictable resulting phenotypes of transgenic or gene-targeted animals. "Animals containing the same exact genetic manipulation exhibit profoundly different phenotypes when present on diverse genetic backgrounds, demonstrating that genes unrelated, per se, to the ones being targeted can play a significant role in the observed phenotype" (e.g. abstract). Sigmund further states that "many of the phenotypes examined in transgenic and knockout models are influenced by the genetic background in which they are studies...Although all mouse strains contain the same collection of genes, it is allelic variation...and the interaction between allelic variants that influence a particular phenotype. These "epigenetic" effects can dramatically alter the observed phenotype and therefore can influence or alter the conclusions drawn from experiments" (e.g. introduction). Mogil et al., 1999 (Pain, Vol. 80, pages 67-82) reports that there are several limitations to the use of mouse transgenic KO models. Mogil teaches that "the embryonic stem (ES) cell lines used to carry the targeted mutation are all derived from various substrains of the 129 strain" and "it is difficult to separate by homologous recombination the 129-derived transgene from tightly linked gene. Even after repeated backcrosses to C57Bl/6, a step most often omitted in the competition to publish, the wild-type and KO populations will differ in their inheritance of so-called "hitchhiking donor gene" alleles". Knockout mutant mice will inherit alleles tightly linked with the gene disruption, leading to "hitchhiking donor gene" alleles from 129 ES cell lines while the wild-type mice will inherit C57BL/6-derived alleles. "[O]bserved phenotypic differences between wild-type and KO mice could, therefore, be due to the targeted

mutation, to allelic variation at one or more of the many unidentified hitchhiking genes, or to an interaction between them" (page 78, left column). In addition, "the background genes from the parent strains can interact with the targeted mutation ("epistasis"), importantly affecting the observed phenotype" (page 78, left column).

In addition, Houdebine, L-M., 2002 (Journal of Biotechnology, Vol. 98, p. 145-160) points out that reintegration of an isolated gene into the genome of an animal by gene microinjection may generate complex and unpredictable biological situations (e.g. p. 146, first paragraph). Houdebine states that "animal transgenics is still suffering from technical limitations" (e.g. abstract). Mercier et al., 1997 ("The modification of milk protein composition through transgenesis: progress and problems," In: Transgenic Animals: Generation and use, Ed. Houdebine LM, Harwood Academic Publishers, The Netherlands pp: 473-482) teach that "much progress remains to be done before routinely using transgenesis for generating farm animals producing milk for non-therapeutic use. In the present state of the art, it is difficult to predict that a construct will be functional because of insufficient knowledge on gene transcript, Pre-mRNA processing, RNA and protein stability. Integration of the microinjected transgene is aleatory resulting in highly variable levels of expression, and possible detrimental effects." (e.g. p. 479, right column).

In view of the inherent unpredictability of the resulting phenotypes of transgenic animals or mice and the lack of any phenotype of the claimed transgenic animals or mice, one skilled in the art at the time of the invention would not know how to use the claimed transgenic animals or mice. For the reasons set forth above, one skilled in the art at the time of the invention would have to engage in undue experimentation to practice over the full scope of the invention claimed.

This is particularly true based upon the nature of the claimed invention, the state of the art, the unpredictability found in the art, the teaching and working examples provided, the level of one of ordinary skill which is high, the amount of experimentation required, and the breadth of the claims.

In addition, claims 17-21, 25, 26 and 28 encompass chimeric animals or mice (genetic mosaics) and a host cell isolated from the claimed chimeric mouse, wherein only a portion of the cells of the animal or mouse comprises the claimed altered ferritin light chain gene because the claims can be interpreted to read on chimeric animals or mice. The phrase "a transgenic animal comprising an altered ferritin light chain gene" in claim 17 can be interpreted to read on a chimeric animal. The specification fails to enable making chimeric animals or mice such that they exhibit any phenotype, including a wild-type phenotype. The specification fails to provide adequate guidance and evidence for how to generate chimeric animals or mice comprising an altered ferritin light chain gene and fails to disclose any phenotype of a chimeric animal or mouse. The method of making genetic mosaic animals or mice is such that each resulting chimera is comprised of a different, unpredictable ratio of cells of various genotypes. This ratio cannot be predetermined. Furthermore, the spatial distribution of cells of each genotype cannot be predetermined. Therefore, the phenotype of chimeric animals or mice is not only dependent upon the genotype of the cells (which is unpredictable as set forth by the state of the art outlined above, for example see Mogil; Sigmund) but is also dependent upon the spatial distribution of the cells and their relative population size. Thus, the phenotype of the chimeric animals or mice encompassed by the claims is highly unpredictable. The specification fails to provide the guidance necessary to overcome this high level of unpredictability to generate a chimeric animal

or mouse exhibiting any specific phenotype or any phenotype other than wild type. As set forth above, without a predictable phenotype, it would require additional and undue experimentation for one of skill in the art to determine a useful phenotype for the claimed chimeric animals or mice and to determine what to screen for. Therefore, without undue experimentation, the skilled artisan would not know how to use the chimeric animals or mice encompassed by the claims.

For the reasons set forth above, one skilled in the art at the time of the invention would have to engage in undue experimentation to practice over the full scope of the invention claimed. This is particularly true based upon the nature of the claimed invention, the state of the art, the unpredictability found in the art, the teaching and working examples provided, the level of one of ordinary skill which is high, the amount of experimentation required, and the breadth of the claims.

Claims 17, 20 and 25 encompass using any altered ferritin light chain (FTL) gene derived from various organisms. The specification fails to enable expressing any FTL variant gene in a mouse by using FTL variant gene sequence other than that set forth by SEQ ID No. 1. The breadth of the claims encompasses using any altered FTL gene derived from numerous organisms other than that described and set forth by SEQ ID No. 1. The specification teaches only one FTL variant gene sequence (SEQ ID No. 1). The specification fails to disclose any FTL gene or FTL variant gene sequence derived from various organisms other than the sequence of SEQ ID No. 1 and the biological function of the protein encoded by said gene sequence. Therefore, the specification fails to enable using any FTL gene or FTL variant gene sequence derived from various organisms other than the sequence of SEQ ID No. 1 to make transgenic animal since insufficient written description has been provided for those gene sequences.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 17-20 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on numerous transgenic animals, such as mice, rats, sheep, pigs, canine, feline, monkeys, baboons, chimpanzees, whales etc., expressing altered FTL gene under the control of various promoters. The claims encompass numerous transgenic animals having various unknown and unidentified phenotypes or having no phenotype. The specification fails to disclose generation of any transgenic animal and also fails to disclose any phenotype of the claimed transgenic animal. The phenotypes of various transgenic animals expressing an altered FTL gene under the control of various promoter were unpredictable at the time of the invention as discussed above. The structural features and phenotypes of the transgenic animals that can distinguish said transgenic animals from corresponding wild-type animals have not been disclosed. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe common attributes or characteristics that identify the claimed transgenic animals, and

because the claimed transgenic animals are highly variant, the disclosure in the present application is insufficient to describe the claimed transgenic animals.

This limited information is not sufficient to reasonably convey to one skilled in the art that applicants were in possession of the claimed transgenic animals. Thus, it is concluded that the written description requirement is not satisfied for the transgenic animals as claimed.

13. Claims 17, 20 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 111 1, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1 117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

The specification has described the nucleotide sequence, encoding the human FTL variant gene, as set forth by SEQ ID No. 1. In the instant case the genus of FTL genes encompassed by the claims lack a written description. The specification fails to describe what DNA molecules other than the nucleotide sequence set forth in SEQ ID No. 1 fall into this genus and it was unknown as of Applicants' effective filing date that any of these DNA molecules would have the

property of encoding a FTL polypeptide having the same structural and functional properties as that encoded by SEQ ID No. 1. There is no evidence on the record of a relationship between the structures of the nucleotide sequences coding for a human FTL variant gene product and the nucleotide sequence set forth by SEQ ID No. 1 that would provide any reliable information about the structure of DNA molecules within the genus. The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification and that is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor has possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641,1646 (1998).

With the exception of the sequence referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by any member of the genus of genes encoding a FTL gene product or variant FTL gene product other than that set forth by SEQ ID No. 1. Therefore, only the FTL gene encompassed by SEQ ID No. 1, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112 first paragraph. Applicants were not in possession, at the time of the invention, of the transgenic animals or mice generated by using various FTL gene sequences other than the disclosed sequence of SEQ ID No. 1. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that "to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention".

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER